NOT FOR PUBLICATION

UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

CELGENE CORP.,	
Plaintiff,	**Civil Action No. 10-5197 (SDW)**
v.	
NATCO PHARMA LTD., et al.,	**Opinion**
Defendants.	

ARLEO, UNITED STATES MAGISTRATE JUDGE

I. INTRODUCTION

This matter comes before the Court on the motion of Defendants Natco Pharma Limited, Arrow International Limited, and Watson Laboratories (collectively, "Defendants") to amend their invalidity contentions. Dkt. No. 321. Oral argument was held on October 22, 2014. For the reasons set forth below, Defendants' motion is **GRANTED-IN-PART** and **DENIED-IN-PART.**

II. BACKGROUND

This litigation arises from Natco's filing of an Abbreviated New Drug Application with the FDA, seeking approval to market a generic version of Plaintiff Celgene Corporation's lenalidomide drug, which Celgene markets under the brand name Revlimid®. Celgene alleges Defendants' proposed generic infringes 18 patents, including U.S. Patent Nos. 7,465,800 (the

"'800 patent"), 5,635,517 (the "'517 patent"), 6,281,230 (the "'230 patent"), 6,555,554 (the "'554 patent"), 7,119,106 (the "'106 patent"), and 8,288,415 (the "'415 patent").

Defendants move to amend their invalidity contentions to add new legal theories and prior art references. Specifically, Defendants seek to add: (1) new invalidity defenses for the '800 patent based upon Judge Wigenton's construction of "hemihydrate" and (2) new prior art references for the '517 patent, '230 patent, '554 patent, '106 patent, and '415 patent (collectively, the "Lenalidomide Patents") "that address Celgene's mischaracterizations of the prior art in its own responses to Defendants' invalidity contentions." Defs. Br., Dkt. No. 321, at 1. The Court shall address the factual background, procedural history, and legal arguments of each category of proposed amendments separately.

III. The '800 Patent

A. Background

On June 8, 2011, Celgene provided Defendants with their proposed claim constructions for approximately 60 claim terms, of which approximately 40 were disputed. One of the '800 patent's disputed terms was "hemihydrate." Celgene offered the following proposed construction: "A hydrate containing approximately half a mole of water to one mole of the compound forming the hydrate." In support of this definition, Celgene cited the '800 patent and two dictionaries. The parties then filed a Joint Claim Construction and Prehearing Statement on July 18, 2011, which contained the following claim chart:

Term	Celgene's Proposal	Defendants' Proposal
Hemihydrate	A hydrate containing approximately half a mole of water to one mole of the compound forming the hydrate.	a solid crystalline form of lenalidomide containing one water molecule for every two molecules of 3-(4-amino-1-oxo-1,3 dihydro- isoindol-2-yl)- piperidine-2,6-dione,

		formally associated with one another within the unit cell in the solid crystalline structure, and which crystal form is specifically identified in the '800 patent as the Form B polymorphic form, and demonstrated in TGA, Karl Fischer analysis, powder X-ray diffraction patterns, IR spectra, and/or DSC analysis, as distinguishable from other polymorphs, such as the anhydrous form

See Dkt. No. 81. The parties filed opening Markman briefs on August 23, 2011 and responsive briefs on October 25, 2011. These briefs were withdrawan as the number of parties and claims in the case continued to expand.

On October 18, 2013, the parties filed another Joint Claim Construction and Prehearing Statement. See Dkt. No. 248. Celgene offered the same proposed construction for "hemihydrate," but provided additional evidence to support its construction. Id. at 8-9.

After full briefing and a claim construction hearing, the Honorable Susan Wigenton, U.S.D.J., issued her claim constructions opinion on May 27, 2014. As to the term "hemihydrate," Judge Wigenton adopted Celgene's construction. See Opinion, Dkt. No. 312, at 6-7.

On June 19, 2014, Defendants moved to amend, arguing that, based upon Judge Wigenton's adoption of Celgene's proposed construction, Defendants could now challenge the '800 patent's validity. Specifically, Defendants argue the '800 patent is invalid for indefiniteness, lack of enablement, and lack of written description. Celgene opposes this motion.

B. Analysis

The District of New Jersey's Local Patent Rules require early disclosure of the patentee's infringement contentions and the alleged infringer's invalidity contentions. Sanofi-Aventis v. Barr Labs., Inc., 598 F. Supp. 2d 632, 637 (D.N.J. 2009). The purpose of such early disclosure, at least in part, is "to further the goal of full, timely discovery and provide all parties with adequate notice and information with which to litigate their cases." King Pharm., Inc. v. Sandoz Inc., Civ. No. 08-5974, 2010 WL 2015258, at *4 (D.N.J. May 20, 2010) (quoting Computer Accelerations Corp. v. Microsoft Corp., 503 F. Supp. 2d 819, 822 (E.D. Tex. 2007)) (internal quotation marks omitted). The rules "are designed to require parties to crystallize their theories of the case early in the litigation and to adhere to those theories once they have been disclosed." King Pharm., 2010 WL 2015258, at *4 (citing Atmel Corp. v. Info. Storage Devices, Inc., No. 95-1987, 1998 WL 775155, at *3 (N.D. Cal. Nov. 5, 1998)) (internal quotation marks omitted). The courts of this district have distinguished this stricter standard from that of the liberal standard to amend a pleading. Astrazeneca AB v. Dr. Reddy's Labs., Inc., No. 11-2317, 2013 WL 1145359, at *2-4 (D.N.J. Mar. 18, 2013). Nevertheless, Rule 3.7 "is not a straitjacket into which litigants are locked from the moment their contentions are served . . . [a] modest degree of flexibility [exists], at least near the outset." Id. at *8-9. Therefore, while "preliminary infringement contentions are still preliminary it is important to recognize that the Local Patent Rules strive to have the parties establish their contentions early on." Id. (internal quotations omitted).

Local Patent Rule 3.7 allows for amendment of contentions "only by order of the Court upon a timely application and showing of good cause." Good cause "considers first whether the moving party was diligent in amending its contentions and then whether the non-moving party

would suffer prejudice if the motion to amend were granted." Dr. Reddy's Labs., 2013 WL 1145359, at *3 (citing O2 Micro Int'l, Ltd. v. Monolithic Power Sys., 467 F.3d 1355 (Fed. Cir. 2006)). In determining whether good cause exists, courts have also considered factors such as: (1) the reason for the delay, including whether it was within the reasonable control of the party responsible for it; (2) the importance of what is to be excluded; (3) the danger of unfair prejudice; and (4) the availability of a continuance and the potential impact of a delay on judicial proceedings. See Oy Ajat, Ltd. v. Vatech Am., Inc., 2012 WL 1067900, at *11 (D.N.J. Mar. 29, 2012).

Therefore, amendment is only permitted when: (1) there is good cause to allow amendment; (2) the motion is timely; and (3) there is no undue prejudice to the adverse party. Jazz Pharm., Inc. v. Roxane Labs., Inc., No. 10-6108, 2012 WL 3133943, at *2 (D.N.J. July 30, 2012).

The Court first turns to whether there is good cause to allow amendment. Local Patent Rule 3.7 provides: "Non-exhaustive examples of circumstances that may support a finding of good cause include (a) a claim construction by the Court different from that proposed by the party seeking amendment . . . ."

Celgene argues that, notwithstanding Rule 3.7's text, a moving party cannot possibly demonstrate good cause when the Court adopts the non-moving party's construction because the moving party was put on notice of the non-moving party's construction when the parties exchange proposed claim constructions. Here, therefore, as Celgene disclosed its proposed "hemihydrate" construction on June 8, 2011, Defendants had known for three years that the Court might adopt the construction that Defendants now contend gives rise to certain 35 U.S.C. § 112 invalidity arguments. In effect, Celgene argues that the phrase "a claim construction by the

Court different from that proposed by the party seeking amendment" in Rule 3.7 should be interpreted as "a claim construction by the Court different from that proposed by either party."

The Court disagrees. Rule 3.7's plain language permits for the possibility of amendment in the exact circumstance before the Court. If the Local Patent Rules were intended to limit amendment to instances where the Court adopts a claim construction different from either of those proposed by the parties, the Rules would reflect that language. Here, Defendants have moved to amend after the Court adopted a claim construction that differs from the construction Defendants proposed. This motion was filed only 23 days after Judge Wigenton issued her Markman opinion. Therefore, good cause exists to amend and the motion is timely.

While Celgene heavily relies upon Prometheus Labs., Inc. v. Roxane Labs., Inc., No. 11-1241 (D.N.J. Aug. 6, 2012), that case is distinguishable. There, because the court concluded that the moving party was fully capable of moving to amend prior to an adverse Markman ruling, the court denied that party's motion to amend after the Markman opinion issued. Id. at 14-15. In this case, however, the number of disputed patents, claims, and claim terms is so great that the Court cannot conclude that Defendants should have moved to amend on June 8, 2011 to address every possible adverse claim construction ruling. Other courts in similar circumstances have reached the same conclusion. See Network Prot. Scis., LLC v. Fortinet, Inc., No. 12-1106 (N.D. Cal. May 9, 2013); cf. Jazz Pharm., Inc. v. Roxane Labs., Inc., No. 10-6108 (D.N.J. Oct. 3, 2014); Astrazeneca Ab v. Hanmi USA, Inc., No. 11-760, 2013 WL 264609, at *2 (D.N.J. Jan. 23, 2013).

The Court must now determine whether amendment would impose undue prejudice on Celgene. In deciding whether Defendants' proposed amendments would unfairly prejudice Celgene, the Court considers whether permitting the proposed amendments would: (1) require

Celgene to expend significant additional resources, or (2) significantly delay the resolution of this case. TFH Publ'ns., Inc. v. Doskocil Mfg. Co., Inc., 705 F. Supp. 2d 361, 366 (D.N.J. 2010).

Celgene argues that, had these invalidity defenses been raised earlier, it would have questioned several Natco 30(b)(6) representatives on topics related to these questions. Next, Celgene claims it would have asked Defendants' Markman expert, Dr. Mark Hollingsworth, additional questions. Finally, Celgene asserts it would need to revise its responses to Defendants' invalidity contentions.

The Court finds that Celgene would not suffer adverse prejudice if amendment is permitted. See Helsinn Healthcare S.A. v. Dr. Reddy's Labs. Ltd., No. 11-3962, 2013 WL 3336859, at *5-6 (D.N.J. July 2, 2013). First, because expert reports have not been exchanged, Celgene will simply be able to address these arguments in their initial reports. Second, if Celgene believes additional fact discovery is necessary, Celgene may request that fact discovery be reopened for the limited purpose of conducting discovery on Defendants' new invalidity contentions.[1] Third, a trial date has not been set. Fourth, additional expenses in amending responses to invalidity contentions does not constitute undue prejudice. TFH, 705 F. Supp. 2d at 377.

Therefore, Defendants' motion to amend as to the '800 patent is granted.

IV. THE LENALIDOMIDE PATENTS

The Court shall now address Defendants' motion to amend its invalidity contentions as to the '517, '230, '554, '106, and '415 patents. Specifically, Defendants seek to add five new prior

[1] The Court takes no position as to whether additional fact discovery is, in fact, necessary based upon the specific defenses that Defendants now wish to assert.

art references, arguing that these amendments will "rebut inaccuracies and misstatements made by Celgene in its own responsive contentions." Defendants' July 23, 2014 Letter, Dkt. No. 335, at 4.

Defendants suggest that they need satisfy the standard for amendment set forth in Local Patent Rule 3.7 because the prior art references at issue will only be used as rebuttal to Celgene's response.

The Court disagrees.

The Local Patent Rules make clear that a party wishing to amend its contentions must demonstrate timeliness, good cause, and an absence of prejudice to the non-moving party. Here, the Court concludes Defendants have, at minimum, failed to demonstrate timeliness and good cause. Defendants' motion to amend was filed on June 19, 2014. While Defendants allege that they did not receive Celgene's most recent responses to invalidity contentions until July 1, 2013, Celgene represents that Defendants have been aware of the responses at issue since January 31, 2013, and Defendants do not appear to challenge this assertion. See Celgene's July 11, 2014 Letter, Dkt. No. 331, at 1-2. Additionally, Defendants have failed to demonstrate that they exercised diligence. See King Pharma., Inc. v. Sandoz Inc., No. 08-5974, at *4 (D.N.J. May 20, 2010). Therefore, Defendants' motion to amend as to the Lenalidomide Patents is denied.

V. CONCLUSION

For the reasons set forth above, Defendants' motion to amend [Dkt. No. 321] is **GRANTED-IN-PART** and **DENIED-IN-PART**. An appropriate Form of Order accompanies this Opinion.

Dated: November 18, 2014

/s Madeline Cox Arleo
United States Magistrate Judge

Orig: Clerk
cc: Parties
Hon. Susan D. Wigenton